

REMARKS

Applicants respectfully request reconsideration of the present application in view of the foregoing amendments and in view of the reasons that follow.

Claims 1-13 are requested to be cancelled. The cancellation of claims does not constitute acquiescence in the propriety of any rejection set forth by the Examiner. Applicants reserve the right to pursue the subject matter of the canceled claims in subsequent divisional applications.

Claim 23 is new. Support for the new claim can be found on page 14 of the Specification. A detailed listing of all claims that are, or were, in the application, irrespective of whether the claims remain under examination in the application, is presented, with an appropriate defined status identifier.

Upon entry of this Amendment, claims 14-23 will remain pending in the application.

Because the foregoing amendments do not introduce new matter, entry thereof by the Examiner is respectfully requested.

Claim Rejections – 35 U.S.C. § 103

Claims 14-17 and 20-22 are rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over WO 01/82875 (“Cutie”) in view of US 5,547,683 (“Yano”) or separately in view of JP 2001342185 (‘185). Claims 14-17 and 20-22 are rejected over US 2004/0106660 (“Kositprapa”) in view of Yano or separately in view of ‘185. Claims 14 and 18-20 are rejected over US 2003/0060488 (“Sugiyama”) in view of Yano. Claims 14-20 are rejected over Sugiyama in view of Cutie or Kositprapa and further in view of Yano. Claims 14-22 are rejected over Sugiyama in view of Cutie or Kositprapa and further in view of ‘185. The Applicants respectfully traverse all of these rejections.

In the prior responses, Applicants presented arguments why the current claims are not obvious over Cutie, Yano, Kositprapa and Sugiyama. Applicants incorporate these arguments by

reference. In particular, arguments focused on 1) the prior art not teaching all of the claim elements, 2) the prior art not teaching the use of a claim element in a fashion similar to the current invention and 3) Applicants position that one of skill in the art would not combine the art to form the currently claimed invention. For example, Applicants argued that Yano's use of HPC-SSL was distinct from the current claims and that the Office has misconstrued Yano. In the current Office Action, the Office replied to Applicants arguments by re-asserting the use of Yano and adding another reference, '185, to most of the rejections. "'185 teaches coating a tablet core with a coating containing HPC-SSL (Derwent Abstract, pg. 6)" Office Action, pp. 10, 12, and 14.

Finally, the Office has suggested "that Applicant show factual evidence (via side-by-side comparison) that the HPC-SSL or SL, as instant claimed yields unpredictable [results]." Office Action, p. 17.

i. Current Obviousness Standard

The U.S. Supreme Court reaffirmed the Graham factors for determining obviousness in *KSR Int'l Co. v. Teleflex Inc.* (No. 04-1350) (U.S., April 30, 2007). The Graham factors, as outlined by the Supreme Court in *Graham et al. v. John Deere Co. of Kansas City et al.*, 383 U.S. 1 (1966), are: 1) determining the scope and contents of the prior art; 2) ascertaining the differences between the claimed invention and the prior art; 3) resolving the level of ordinary skill in the pertinent art; and 4) evaluating evidence of secondary consideration. The Supreme Court recognized that a showing of "teaching, suggestion, or motivation" to combine the prior art to meet the claimed subject matter could provide a helpful insight in determining whether the claimed subject matter is obvious under 35 U.S.C. § 103(a) and held that the proper inquiry for determining obviousness is whether the improvement is more than the predictable use of prior art elements according to their established functions. The Court noted that it is "important to identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the [prior art] elements" in the manner claimed and specifically stated:

Often, it will be necessary . . . to look to interrelated teachings of multiple patents; the effects of demands known to the design community or present in the marketplace; and the background knowledge possessed by a person having ordinary skill in the art, all in order to determine whether there was ***an apparent reason to combine the known elements in the fashion claimed*** by the patent at issue. To facilitate review, this analysis should be made explicit.

KSR Int'l Co. v. Teleflex Inc., slip op. at 14 (emphasis added).

In addition, as provided in MPEP 2141: “Objective evidence relevant to the issue of obviousness must be evaluated by Office personnel...Such evidence, sometimes referred to as “secondary considerations,” may include evidence of commercial success, long-felt but unsolved needs, failure of others, and unexpected results.” As discussed below, the cited art cannot render the claimed invention obvious.

ii. Unexpected Results

The current Specification provides data using side-by-side comparisons that the currently claimed invention yields unexpected and superior dissolution properties and results. Experimental Examples 1-3 test the dissolution properties of numerous Examples and Comparative Examples from the Specification to show the difference and superior dissolution properties of the currently claimed invention. Data from the Specification is shown below along with an explanation of the superior dissolution properties shown.

In Experimental Example 2, a comparison of the dissolution profile for two examples covered by the claims, Example 7 (prepared with HPC-SL) and Example 8 (prepared with polyvinyl alcohol-PEG), is compared to a sample not covered by the claims, Comparative Example 1 (prepared with L grade). The comparison is shown below:

TABLE 2
Dissolution profiles (%) of pioglitazone hydrochloride
Time

	15 min.	30 min.	45 min.	60 min.
Example 7	62.0	76.5	83.5	86.2
Example 8	80.6	89.4	91.5	91.5
Comparative Example 1	29.9	44.2	55.8	65.3

The dissolution for the claimed Examples in comparison to Comparative Example 1 is more than twice as fast at 15 min. and continues to maintain a significant statistical difference over the 60 minutes.

In Experimental Example 3, a comparison of the dissolution profile for an example covered by the claims, Example 12 (prepared with HPC-SL), is compared to a sample not covered by the claims, Comparative Example 2 (prepared with L grade). The comparison is shown below:

TABLE 3
Dissolution profiles (%) of pioglitazone hydrochloride
Time

	15 min.	30 min.	45 min.	60 min.
Example 12	66.2	92.5	97.9	98.8
Comparative Example 2	33.8	68.6	83.2	90.6

The dissolution for the claimed Example in comparison to Comparative Example 2 is nearly twice as fast at 15 min. and continues to maintain a significant statistical difference over the 60 minutes.

Similar dissolution profiles to the unexpected results shown above were also identified in Experimental Example 1. In Experimental Example 1, two examples covered by the claims, Example 10 (prepared with HPC-SSL) and Example 11 (prepared with polyvinyl alcohol-PEG), showed similar dissolution profiles to Examples 7-8 and 12 above, as compared to the Comparative Examples.

TABLE 1
Dissolution profiles (%) of pioglitazone hydrochloride
Time

	15 min.	30 min.	45 min.	60 min.
Example 10	60.6	77.4	84.3	88.3
Example 11	71.2	78.1	84.7	86.9

Based on these data, the Specification shows that under the rotating basket method (Experimental Example 1) and the paddle method (Experimental Examples 2 and 3), the currently claimed inventions show an unexpected and superior result in dissolution profiles important in providing therapeutic benefit to patients. These results could not have been predictable to one of skill in the art and support the non-obviousness of the current claims.

Based on these results and the arguments provided previously, Applicants respectfully request that the rejections be withdrawn.

CONCLUSIONS

The Applicants believe that the present application is now in condition for allowance and thus respectfully request favorable reconsideration of the application.

The Office is invited to contact the undersigned by telephone if a telephone interview would advance the prosecution of the present application.

The Office is hereby authorized to charge any additional fees which may be required regarding this application under 37 C.F.R. §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 19-0741. If any extensions of time are needed for timely acceptance of papers submitted herewith, the Applicants hereby petition for such extension under 37 C.F.R. § 1.136 and authorize payment of any such extensions fees to Deposit Account No. 19-0741.

Respectfully submitted,

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Date _____

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